IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	
Beck, et al.	Examiner: JAGOE, DONNA A.
Serial Number: 10/800,992	Group Art Unit: 1614
Filed: 3/15/2004	
For: PRESERVED CYCLODEXTRIN-CONTAINING COMPOSITIONS	

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
Washington, DC 20231

Dear Sir,

I, Gary Beck, hereby declare as follows:

1. I am the inventor of the invention claimed in presently pending claims 31-50 of the present pending patent application. I earned a BS in Animal Science from California Polytechnic State University, Pomona in 1977 and a M.S. in Chemistry from California State University, Long Beach in 1990. I have been employed at Allergan, Inc. in various scientific positions since 1988, and presently hold the position of Senior Director, Global Project Management, Analysis at Allergan.

2. I understand that these claims, which I have reviewed, have been rejected by the United States Patent and Trademark Office as allegedly obvious over the combination of Lofftson et al., U.S. Patent 5,472,954, Remington' Pharmaceutical Sciences (U), Lipari U.S. Patent No. 4,383,992, and further in view of Dziabo et al. U.S. Patent No. 5,424,078 (collectively, the References).

3. Claim 31 and all the remaining claims are directed to an ophthalmnic aqueous solution containing prednisolone acetate, a cyclodextrin derivative, and a preservative component selected from a chlorite component and a sorbate component. These claims are consistent with my invention as disclosed in the patent application, based on the discovery

that only certain preservatives, such as chlorite and sorbate, substantially maintain their preservative efficacy in the presence of cyclodextins.

4. The Office Action indicates that Lofftson is drawn to prednisoline compositions containing an α- or β- cyclodextrin to enhance their solubility. Remington's is cited as directing one toward substituting prednisolone acetate for prednisolone in the compositions of Lofftson. Liparti is characterized as disclosing prednisolone acetate and a cyclodextrin in a solution. Dziabo is cited as disclosing chlorite preservatives in ophthalmic solutions.

5. I have reviewed the June 2, 2008 Office Action. The Office Action appears to concentrate almost exclusively on whether or not a composition containing prednisolone acetate and cyclodextrin would be obvious based upon Lofftson, Remington's, Liparti and Dziabo.

6. However, the claims are also drawn to the combination of cyclodextrin derivatives in a prednisolone acetate ophthalmic composition with an effective amount of a preservative selected from chlorite and sorbate. This combination is directly related to a surprising aspect of the invention; the fact that the objectively determined preservative efficacy of these preservatives are not substantially affected by the presence or absence of cyclodextrin (see e.g., Specification, Examples 1 and 2, pages 16 and 17). This is particularly surprising in light of the Specification's disclosure that other commonly used preservatives such as benzalkonium chloride (BAK) are less effective in the presence of cyclodextrins and cyclodextrin derivatives than in the absence of these agents. Thus, the Specification indicates that 50 ppm BAK is sufficient to enable a composition to pass the United States preservative efficacy test (USPET) in the absence of cyclodextrin, but 100 ppm BAK in the presence of 10% or 20% cyclodextrin is insufficient to enable the composition to pass USPET. *See* Specification, Examples 3-9, pages 17-18.

7. As additional support, Examples 22-29 are drawn to compositions containing prednisolone acetate and 8% sulfobutylether β cyclodextrin. Compositions 22-25 also contained 0.15% (1500 ppm) BAK, and failed the USPET (even when 0.5% sorbate was present). However, compositions 26-29 contained 0.0075% stabilized chlorine dioxide and passed USPET. Also, compositions 31-33 contain prednisolone acetate, 8% sulfobutylether β cyclodextrin, and no stabilized chlorine dioxide or BAK but do contain 0.5% sorbate; these compositions pass USPET.

8. None of Lofftson, Remington's, Liparti and Dziabo discuss or even suggest using chlorite or sorbate in combination with a cyclodextrin in an aqueous composition, regardless of the active ingredient, much less specifically in combination with prednisolone acetate.

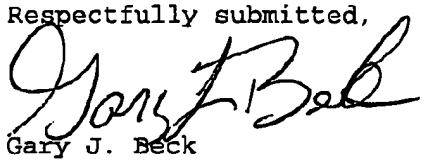
9. The data referred to above was generated in my laboratory and was completely surprising and unpredicted by my staff or me at the time the experiments were conducted. I consider that my colleagues and I were, at the time that this patent application was filed, well-versed in this area of scientific endeavor and were of greater than ordinary skill in the art. I strongly believe that my colleagues and I could not have predicted the surprising nature of the preservative efficacy of a composition containing chlorite or sorbate as putative preservatives in combination with a cyclodextrin, irrespective of the nature of any active ingredient also present in the composition. Therefore, I believe that a person of ordinary skill in the art would also have been unable to predict, and would not have considered obvious, the claimed prednisolone acetate composition containing an effective amount of the preservatives chlorite or sorbate in combination with a cyclodextrin.

10. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the

Serial No. 10/800,992
Docket No: D-2804CON2

present application or any patent issuing thereon.

Respectfully submitted,



Gary J. Beck
Senior Director
Global Project Management
Allergan, Inc.